135919174230 8811030252 7927635.0232558 67213813030 96342131760 10748280.488889 5565674.3921569 143861693686 17870430.357143 19208472.240506 7547477.171875 15650479394 27394142.959459 67232732292 30053829840 13210022812 23436878448 118364274006 131306901150 24586529160 21994877.155556 116820512400 30464659050 99364591745 20185914300 165086647650 27011526 65770976405 21907792.291667 75396279.5625 143057362.21429 118039891.5 4528393.4285714 20300717.548387

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Ngã £ y ãªâ € ° € GENERAL 80 GLOSSION 81 QUALITY MANAGEMENT IN MEDICINALS STRUCTURING: Philosophy and Essential Elements 85 Quality Quality System Quality Risk Management Risks Product Quality Review 85 88 88 Good manufacturing practices For pharmaceutical products 90 sanitation and hygiene 91 Qualification and validation 91 Complaints 92 RECORUTE OF PRODUCTS 93 Production, Key and other activities 94 94 94 95 96 The contract Contract, contract, contract, self-inspection contract, quality audits and items and items of supplier approval for self-inspection of the self-inspection team frequency Self-inspection report of Auto-inspection Audit Audit Audit and Approval 97 98 98 98 98 98 The current document is a review £ The good manufacturing practices for pharmacoms: Main Principles, previous Ly published at Who Technical Report Series, n. 961, 2011, Annex 77 WHO Committee of Specialties of Specifications for FarmAutic Preparations Forty and Eighth General Personal Personal Key 103 11 Personal Hygiene 103 12 Installations 104 104 105 106 107 108 storage the weighing areas of the production areas of quality control reas 13 equipment 108 14 Materials 109 110 110 111 112 112 112 113 113 114 114 115 General Starting Materials Packaging Materials Intermediate Materials Rejected, recovered, reprocessed rivers and rehabilated products withdrawn products returned goods reagents and patterns of Mother Culture Mother Various Materials 15 documentation who is technical reporting. 986, 2014 General Documents Necessary 78 99 99 99 16 Good practices cross contamination and bacterial contamination during production processing operationsoperations 17 Good practices in quality control Control of starting materials and intermediate products, in bulk and finished Test requirements Batch registration analysis Stability studies References 115 116 125 125 126 127 128 129 131 132 134 134 134 135 Annex Introduction The first WHO text on good manufacturing practices (GMP) was prepared in 1967 by a group of consultants at the request of the 20th World Health Assembly (WHA20.34 Resolution) Subsequently, it was submitted to the XXI World Health Assembly under the title Design of requirements for good manufacturing practice in the manufacture and quality control of medicines and pharmaceutical specialties and was accepted The revised text was discussed by the WHO Specialist Commission on the specifications for pharmaceutical preparations in 1968 and published as an annex to its twenty-second report. The text was then reproduced (with some revisions) in 1971 in the Supplement to the second edition of the International Pharmacopoeia In 1969, when the World Health Assembly recommended the first version of the WHO Certification System on the quality of pharmaceutical products that move in international trade in WHA22.50 resolution, at the same time accepted the GMP text as an integral part of the revised versions of the Certification System and the GMP 1975 text were adopted in WH65. Since then, the Certification System has been extended to include certification of: – veterinary products administered to food-producing animals; – starting materials for use in dosage forms, when they are subject to control by legislation both in the exporting Member State and in the importing Member State; – information on safety and efficacy (WA41.18, 1988) In 1992, the revised GMP projects were submitted in three parts, of which only parts and reproduced in this document (1). “GMP quality managementStrong: Philosophy and essential elements, describes the general concepts of quality guarantee (QA), as well as the main components or subsystems of the GMP, which are joint responsibilities of superior gesture and production management management. The quality and quality control these include hygiene, validation, self-inspection, personal, installations, equipment, materials and documentation Quality control and control, provides guidance on actions to be taken separately by the production and quality control personnel for the implementation of the general printers of QA these two parts were later complemented by other guidelines that are integral parts of this GMP for pharmacomatic products all these texts are disposed of in the Web Page of Medicines (http.www.who.int/medicines/organizaajao/qsm/activities /QUALITYSSURANCE/GMP/GMPCOVER HTML) 79 WHO EXPERT COMMITEE ON SPECIFICATIONS FOR PREPARATION Forty-eight WHO TECHNICAL REPORT SERIES REPORTING STARES IN 986, 2014 Consider GMP developments occurred in intervening years, and important national and international documents, including new reviews, appeared (2-5). Thus, there is a need to revise the main princes and incorporate the concept of validation among other feedback items discussed during the WHO guidelines for Quality Guarantees Guidelines, Quality Control (QC) and Transfer. Of technology on July 27-31, 2009, the need was identified to incorporate a new section on â € Í € quality revision in Chapter 1: © This, the updates were suggested to further improve the guidelines these include the concept of risk management, replacing â € œMedicinasâ € œMedicinas and introducing the concept of Â € œ quality unit € During 2012 the secretariat was taken that the current good manufacturing practices (GMP) for pharmaceuticalThe main principles, published as Annexes to the WHO Technical Reports Series, No 961, 2011, would need to be updated (warranty/production/en/index. html - Quality assurance of pharmaceutical products: a compendium of guidelines and related materials) The WHO Specialist Committee on Pharmaceutical Preparations discussed the need for an update during its forty-seven meeting and agreed to pursue the issue according to the following sections were updated in the newly revised version and, after the usual consultation process, were presented to the Specialists Committee of forty-eight for adoption: 80 Section 2: Section 7: Section 17: Pharmaceutical Quality System Good manufacturing practices for pharmaceuticals Production, analysis and other activities 17 Good practices in quality control General considerations Licensed pharmaceutical products (marketing authorization) must be manufactured only by licensed manufacturers (shareholders of a manufacturing authorization) whose activities are regularly inspected by the competent national authorities This guide to GMP will be used as a standard to justify the status of GMP, which constitutes one of the WHO Certification System elements on the quality of pharmaceutical products moving in international trade, through the evaluation of manufacturing authorization applications and as a basis for the inspection of manufacturing facilities It may also be used as training material for government drug inspectors, as well as for production, QC and QA in the Industry Annex The guide is applicable to operations for the manufacture of medicines in their completed dosage forms, including large-scale processes in hospitals and the preparation of supplies for use in clinical trials. Good practiceThe following should be considered general guides, 2 and can be adapted to meet individuals However, the equivalence of alternative approaches to QA should be validated the guide as a whole encompasses insurance aspects for the workers involved in the manufacture or in the protection of the environment: these are The normally governed by national legislation a new concept of hazard -related danger -related dwarfs and safety risks was also recently recommended (WHO TECHNICAL REPORT SERIES, 961, Annex 7) The manufacturer must ensure workers' security and take the necessary measures to avoid the pollution of the external environment. They should be used when disposed, along with other names designated glossal the following definitions are applied to the terms used in this guide they may have different meanings in other contexts ingredients active pharmacoms (API) any substance or mystur that of substances intended to be used in the manufacture of a form of pharmaceutical dosage and which, when used, becomes an active ingredient of this form of pharmacist dosage. Such substances are intended to provide pharmacolical activity or other direct effect on diagnosis, cure, mitigation, treatment or disease prevention or to affect the structure and function of the lock From the body a closed space with two or more doors, which is filed between two or more rooms, for example, from different cleaning classes, in order to control the air flow between these rooms when an airlock need to be inserted to insert It is designed for use by persons or for goods and / or equipment authorized to the person recognized by the national regulatory authority and having the responsibility to ensure that each batch of finished product was manufactured, tested and approved for release in accordance with compliance with the laws and regulations in force in this batch of paãs (or A set amount of starting material, packagingor product processed in a process or process of proceedings to be expected to be homogeneous times, it may be necessary to share a lot into a sub-baptches, which is later gathered later To form the word â € œDeveâ € in the text means a strong recommendation 81 WHO TECHNICAL REPORT SERIES NO 986, 2014 WHATE EXPERITTEE ON SPECIFICATIONS FOR PREMACTING PREPARATIONS Forty -eight Relation 82 The final homogeneous Lot In the case of terminal sterilization, the size of the lot is determined by the capacity of the autoclave in the containing manufacturing, the lot must correspond to a defined fraction of the production, characterized by Its intended homogeneity the size of the lot can be defined as a fixed amount or as the amount produced in a number of fixed time batch (or batch. exclusively a lot in labels, its lots and cer records corresponding corresponding dwarfs, etc. records of lots all the associated documents are manufactured by a batch of bulk product or finished product they provide a history of each batch of product and all relevant circumstances to quality From the final mass product product any product that has completed all processing steps at ©, but not including, the end of packaging calibration the set of operations that establish, under specific conditions, the relationship £ o between values indicated by an instrument or system of measurement (especially weighing), record and control, or the values represented by a material measure, and the corresponding known values of a standard Reflection Limits for acceptance of measurement results must be established a clean area with defined environmental and microbial contamination, constructed and used to reduce the introduction £ o, generation and retained contaminant (or delivery) the amount of a pharmacist or pharmacist, made by a manufacturer and provided at the same time in response to a given request or order the shipment may include one or more packages or containers and may include more material belonging to of a batch contamination by the undesirable introduction of quamic or microbioological, or foreign, in or in an initial or intermediate material during production. , sampling, packaging or re -eating, storage or transportation operating an operation in the manufacturing process that can cause variation in the quality of the contaminated pharmacation product contaminated §Ion of an initial material, intermediate product or finished product with another initial material or product during the finished product of producing a finished dosage form that has suffered all factory phases , including packaging in its final container and labeling in the control Process checks performed during production in order to monitor and, if necessary, adjust the process to ensure that the product is in accordance with its specifics the control of the environment or equipment also m can be considered as part of the internal control of the intermediate product of the partially processed product annex that must be subjected to new manufacturing steps before becoming a bulk product product. With a volume of 100 ml or more in a container of the Dosing Forms finished all the purchase operations of materials and products, production, quality control (QC), release, storage and distribution of pharmaceutical products, and the manufacturer of related controls a company that performs operations such as producing, packaging, reemblating, labeling and relation of authorization of pharmacation marketing (licensing product, registration certificate) a document legal Regulatory Authority of Medicines that establishes the composition and detailed formulation of the product and the pharmacopoeial or other recognized specifications of its ingredients and the final product, and includes packaging, labeling and life fan detail ÃºLY or set of documents specifying starting materials with their quantities and packaging materials, along with a description of the necessary procedures and precautions to produce a specified quantity of a finished product, as well as the instruction Processing, including controls in process. Documents that serve as the basis for batch documentation (blank in lot) packing all operations, including filling and labeling, which a bulk product must pass to become a product to fill in a product It is river in assistance conditions or a intended product intended to be terminal sterilized, usually would not be considered part of Ps of any material, including printed material, employed in the packaging of a PHARMACTIC, but excluding any external packaging used for transportation or remittance of packaging materials referred to as a business or secondary according to whether they should or do not be in direct contact with the product product, any material or material Product intended for human or veterinarian use presented in its form of finished dosage or as a starting material for use in this form of dosage, which is subject to control by pharmacation legislation In the state of exportation and/or the state production of imports all the operations involved in the preparation of a pharmacist product, from the receipt of materials, through the material Processing, packaging and re -eating, labeling and designation, to the conclusion of the qualification of the product finished that any installations, systems and items of equipment Work correctly and andlead to expected results The meaning of the word “validation” is sometimes extended to incorporate the concept of qualification 83 WHO Technical Report Series No 986, 2014 WHO Expert Committee on Specifications for Pharmaceutical Preparations Report forty-eight 84 quality assurance View Part (6) Quality control See Part (6) Quality unit (6) An independent organizational unit of production that meets quality assurance (QA) responsibilities and quality control (QC) This can be in the form of separate QA and QC units or a single individual or group, depending on the size and structure of the quarantine organization The status of start or packaging materials, intermediates or bulk or finished products physically isolated or by other effective means, while a decision is awaited in its release, rejection or reprocessing reconciliation A comparison between the theoretical amount and the recovery of the actual quantity The introduction of all or part of previous batches (or distilled solvents and similar products) of the quality required in another batch at a defined stage of manufacture Includes removal of waste impurities to obtain a pure substance or the recovery of materials used for a separate reprocessing Subjecting all or part of a batch or batch of a drug in the process, intermediate bulk process (end biological average) or bulk product of a single batch or batch for a previous step in the validated manufacturing process due to non-compliance with pre-determined specifications Processing procedures are provided as occasionally necessary for biological medicinesThe rework is an unexpected occurrence and is not prevailing as part of the authorization of trading of self-relieving premises that provide complete and total separation Of all aspects of an operation, including the movement of personnel and equipment, with well -established procedures, controls and monitoring this includes fanic barriers, as well as separate air handling systems, but does not necessarily imply two specific Distinct and separated from buildings. A list of detailed requirements with which the products or materials used or obtained during the manufacture should be conform. They serve as the basis for the quality assessment standard operation procedure (SOP) an authorized written procedure providing instructions for the performance of operations no. necessarily specific from a particular product or material (for example, equipment operation, maintenance and cleaning; validation; installation cleaning and environmental control; sampling and inspection) Some SOPS can be used to complement the specific documentation of the master and the production of product lots Annex Starting Material Any substance of a defined quality used in the production of a pharmaceutical product , but excluding the validation of packaging materials to prove, according to the Principles of GMP, that any procedure, process, equipment, material, activity or system really leads to the expected results (see too © M Qualification) Quality Management in the Strike of Medicines: Philosophy and Elements ESS In the induction of medicines in general, quality management is generally defined as the aspect of the management function that determines and implements the quality of the quality, ie the Interan §Ion and global direction of an organization in relation to quality, as formally expressed and authorized by the superior management the elements of the basic elements of of quality: â € “An adequate infrastructure or â € œIt quality, covering the organizational structure, procedures, processes and and – – systematic actions necessary to ensure the proper confidence that a product (or service) meets the requirements for quality All of these actions are called “QA” Within an organization, QA serves as a management tool In contractual situations, QA also serves to generate trust in the supplier The concepts of QA, GMP, QC and quality risk management (QRM) are interrelated aspects of quality management and must be the responsibility of all personnel They are described here to emphasize their relationship and their fundamental importance for the production and control of pharmaceutical products Pharmaceutical Quality System 1.1 Principle The manufacturer must assume responsibility for the quality of pharmaceuticals to ensure that they comply with the marketing authorization requirements and do not put patients at risk due to inadequate safety, quality or effectiveness Good manufacturing practices for pharmaceuticals, Part One In: WHO Specialist Committee on Specifications for Pharmaceutical Preparations Thirty-second Geneva report, World Health Organization, 1992, Annex (WHO Technical Report Series, No 823); and in: Quality assurance of pharmaceutical products A compendium of guidelines and related materials Volume 2, 2nd updated edition Good manufacturing and inspection practices Geneva, World Health Organization, 2007; and in: Quality assurance of pharmaceutical products A compendium of guidelines and related materials Geneva, World Health Organization, 2010 (CD-ROM) 85 WHO Expert Committee on Specifications for Pharmaceutical Preparations Report of Forty-eight The achievement of this quality goal is the responsibility of senior management and requires the participation and commitment of the team in many different departments and at all levels within the company, the suppliers of the company and theTo achieve this quality goalThere must be a pharmacomal quality system (PQS) comprehensively and correctly implemented, incorporating GMP and QRM 1.2 Senior Management, has the final responsibility to ensure that an effective PQS is in force, is properly resources, and that functions, responsibilities and authorities are defined, communicated and implemented throughout the leadership of the administration of the organization and active participation in the PQS is essential that this leader must guarantee the support and the support Team commitment to all the other than organizing sites to PQS WHO TECHNICAL REPORT SERIES NO 986, 2014 1.3 Quality management is a comprehensive concept that encompasses all issues that individually or collectively influences the quality of a product . , incorporates the GMP and other factors, including those outside the scope of this guide, such as design and product development 86 1.4 GMP, applies to life cycle stages since the manufacturing manufacturing manufacturing The transfer of technology and commercial manufacturing, to the discontinuation of the product, the PQs can extend the life of pharmaceutical development -cycle cycle stupid and should facilitate innovation And the improvement containing and strengthening the connection between pharmacomatic development activities and manufacturing, all parts of the PQs must have proper resources and maintained, including supply of competent personnel, installations, equipment and Suitable installations 1.5 The appropriate PQs for the manufacture of pharmacation products must ensure that: a) the accomplishment of the product is reached projecting, qualifying, planning, implementing, maintaining and continually improving a system that allows delivery consistent products with appropriate quality b) the knowledge of the product and the process is managed in all the life cycle stages; c) Pharmacomatic products are projected and developed in a way that takes into account GMP requirements and other associated media that Specific Specialties Committee for Farmuctic Preparations Forty and eighth Relation (F) Details (F) Packaging Operations performed, including refreshing equipment and packaging lines used and, when necessary, the instructions to keep the product if it is not packaged or a returning product record that was packaged in the storage area; (g) Whenever possible, samples of the printed packaging materials used, including emits with the approval for impression and regular verification (when appropriate) of the number of the lot, expiration date and any additional impression; (h) Notes on any special problems, including details of any deviation from packaging instructions, with written authorization by an appropriate person; (i) the quantities and the number of reference or the identification of all printed packaging materials and mass -used, used, destroyed or returned to the stock and product quantities obtained to allow standard operating procedures to allow Proper reconciliation 15.31SOPS AND ASSOCIATED REGISTERS OF AREAES OR, WHERE, THE CONCLUSIONS Achieved must be disposed of: WHO Report Technical Series No 986, 2014 (A) (B) (C) (d) 122 (e) (f) (g) (h) (i) Mounting and validation equipment; analtatic apparatus and calibration; maintenance, cleaning and sanitization; Personnel issues, including qualification, training, clothing and hygiene; environmental monitoring; pest control; complaints; records; Returns 15.32 There must be pops and records for the receipt of each delivery of starting material and principle packaging material and 15.33 Receipt records shall include: (a) the name of the material in the delivery note and the (b) the name and/or material of the material â € œein-huesea € if different from (a); (c) the date of receipt; Annex (d) (E) (f) (g) (h) the name of the supplier and, if possible, the manufacturer's name; Lot or number of manufacturer's reference; the total quantity, and the number of containers received; the number of batch attributed to the receipt; any relevant comment (for example, 15). There should be SOPS for internal labeling, quarantine and storage of starting materials, packaging materials and other materials, as appropriate 15.35 SOPS must be disposed for each instrument and equipment (eg use, calibration, cleaning, maintenance £ o) and placed close proximity to the equipment 15.36 there should be sops for sampling, which specifies the person (s) authorized to take samples 15.37 The sampling instructions should include: (a) the whole sampling and the sampling plan; (b) the equipment to be used; (c) any precautions to be observed to avoid the contamination of the material or any deterioration of its quality; (d) the quantity (s) of sample (s) to take; (e) instructions for any required subdivisions of the sample; (f) The type of sample containers (EPS) to be used, and observed) as a normal sampling. There must be a SOP describing the details of the lots (batch) numbered system in order to ensure that each batch of intermediate product, in bulk or finished is identified with a number of specific lot 15.39 the SOPS to Namers of lots that are applied to the processing phase and respective packaging phase should be related to the other 15.40 the SOP to numeration in the lot must ensure that the same batch no. the being used repeatedly; This also applies 1541. For example, in a onboard diary, the registration must include at least the date of allocation, product identity and size 123 WHO OMS Committee of specifications for specification for Farm -by -Forty and Eighth preparation. Report 15.42 There should be written procedures to test materials and products at different manufacturing stages, describing the mothers and equipment to be used, the tests performed must be recorded 15.43 dwarf records should include by minus the following data: (a) the name of the material or product and, when applicable, the dosage; (b) the number of the lot and, when appropriate, the manufacturer and/ or the supplier; . (d) test results, including observations and calculations, and refreshment to any specifications (limits); (e) date (s) and no. (f) the initials of the people who performed the test; (g) the date and initials of the people who verified the tests and the boards, when appropriate; . Written in writing must be disposed for materials and products and, in particular, for release for the sale of the product finish by an authorized person who is the case of tuition reports No. 986, 2014 15.45 records They must be maintained from the distribution of each batch of a product in order, for example, to facilitate the recall of the lot, if necessary, 124 15.46 records must be kept for the main and critical equipment, as appropriate, of Any validates, calibrations, maintenance, cleaning or repair operations, including dates and the identity of the people who performed these operations 15.47 The use of main and striking equipment and the areas where the products have been processed registered in chronological order 15.48 there must beProcedures that attribute the responsibility for cleaning and sanitation and describe in detail the hours of cleaning, all, equipment and materials to be used and installations and equipment to be cleaned. Such written procedures must be followed by Annex 16. good practices in production 16.1. Production operations must follow procedures clearly defined in accordance with the authorization of manufacturing and marketing, with the objective of obtaining products of the required quality. The authorization of the deviation must be approved in writing by a designated person, with the involvement of the QC Department, when appropriate 16.4 the verification of income and the reconciliation of quantities must be performed as Necessary to ensure that there is no discrepancy outside the acceptable limits 16.5 Operations in different products should not be performed simultaneously or consecutively in the same room or area unless you are not There is a risk of mixture or cross contamination 16.6 at all times during processing, all materials, bulk containers, main equipment items and, if so, the rooms and packaging lines which is being used should be labeled or otherwise identified with an indication of the product or material that is being processed, its force (when applicable) and the number of the lot when applicable , this indication should also mention the production phase in some cases, it may also be to record the name of the previous product that was processed 16.7 Access â £ o It should be restricted to the authorized person 16.8 normally, medical products should not be produced in themselves or with equipment intended for the production of pharmacist products 16.9 the controls in the process. Generally performed within the production area the performance of these controls in the process should not have no negative effect on product quality or other product (for example, cross -contaminated or mixture) 125 who Expert Committee on Specifications for Farmaic Preparation Forty -eight Reporting PREVISION OF CROSS AND BACTERIAN CONTAMINATION DURING PRODUCTION 16.10 When dry materials and products are What is used in production, special precautions should be taken to avoid generation and provisional dust dissemination must be done for adequate air control11. This risk of accidental cross contamination arises from uncontrolled dust release, gases, particles, vapors, sprays or organisms of materials and products in process, residence in equipment, intruders and clothing. of operators, skin, etc. The significance of this risk varies with the type of contaminant and the contaminated product among the most dangerous contaminants are highly sensitizing materials, bio -ogical preparation, such as living organisms, certain hormones, cytothanic substances and other materials Highly active products where contamination is susceptible to being more significant are those administered by injections or applied to open wounds and those data in large doses and / or over a long time sound © Rie of Reporting OMS No 986, 2014 16.12 The cross -contamination may be avoided by the adoption of proper technique or organizational measures, for example: 126 (a) accomplishment The production of dedicated and self-sufficient (which are The production processes (b) of campaign production (separation in time) followed by proper cleaning, according to a validated cleaning procedure; (c) air supply and non -contaminated materials; (D) reduction of the risk of contamination caused by recirculation or reentry of contaminated materials. Processing Operations 16.15 Before any processing operation is started, measures should be taken to ensure that the work area and the equipment is cleaned and free from any materials, products, product residences, strokes or necessary documents for the current operation 16.16 Any control in the necessary process and environmental controls must be performed and recorded 16.17 The empirms must be instituted to indicate equipment failures or services (for example, water, gaps) For defective equipment removal should be used. After use, production equipment should be cleaned without delay in accordance with detailed and stored written procedures in clean and dry condition in a separate area or in a way that will prevent contamination £ o 16.18 The time limits for storing equipment after cleaning and before use must be declared and In the relevant data 16.19 containers for filling should be cleaned before filling the attention should be given to avoid and remove contaminants, such as glass fragments and metal particles 16.20, their significant deviation from expected yield should be recorded and investigated 16.21Checks should be performed to ensure that the pipelines and other equipments omitted to transmit products from one area to another are connected in the correct way 16.22pipes Repair and maintenance operations should not be at risk for the quality of the packaging operations of products 16.25 when the program for packaging operations is being set up, special attention should be paid to minimize the risk of cross-contamination, mixes u different replacements products should not be packaged nearby unless there is physical segregation u an alternative system which will provide equal warranty 16.26 before the start of the packaging operations, measures should be taken to ensure the printing area ofand free of previously used products, materials or documents which are notfor the current operation The line clearance must be carried out according to an appropriate procedure and checklist, and registered 16.27The name and batch number of the product being treated must be displayed in each packaging station or line WHO Technical Report Series No 986, 2014 16.28 Normally, filling and sealing should be followed as soon as possible by labeling If the labeling is delayed, appropriate procedures must be applied to ensure that no mixture or disagreement can occur 128 16.29 The correct performance of any printing (e.g. code numbers or expiration dates) made separately or in the packaging course must be checked and registered Attention should be paid for hand printing, which should be re-branded at regular intervals 16.30 Special care should be taken when cutting labels are used and when overlap is performed out of line, and in manual packaging operations Roll-feed labels are normally preferable to cut labels in helping avoid mix ups Online verification of all labels by automated electronic means can be useful in preventing mixes, but checks should be made to ensure that any e-code readers, label counters or similar devices are working properly When the labels are manually attached, the control controls in the process must be carried out more frequently 16.31 The printed and recorded information on the packaging materials must be distinct and resistant to the dessposition or deletion of Annex 16,32 Samples taken from the packaging line should not be returned 16,33 Products that have been involved in an unusual event during packaging should be reintroduced in the processafter special inspection, investigation and approval by authorized personnel A detailed record must be kept of this operation 16.34 Any significant or unusual discrepancy observed during the reconciliation of bulk product quantity and printed packaging materials and the number of units produced must be investigated, satisfactorily responsible, and registered before releasing 16.35Upon completion of a packaging operation, any unused packaging material encoded should be destroyed and the recorded destruction A documented procedure requiring batch release materials to be submitted before return. Any divergence or failure of a batch to meet production specifications should be carefully investigated Research should, if necessary, extend to other lots of the same product and other products that may have been associated with specific failure or discrepancy A written record of the investigation must be done and must include completion and follow-up action 17 Good practices in quality control 17.1 QC is the part of the GMP concerned with sampling, specifications and testing, and with the organization and documentation that ensure that the necessary and relevant tests are actually performed and that the materials are not released. Production QC independence is considered fundamental 17.3 Each manufacturer must have a QC function The QC functionWhether it is independent of other departments and, under the authority of a person with appropriate qualifications and experiences, appropriate resources must be disposed to ensure that all CQ agreements are effectively and trustworthy, the basic requirements for the CQ are the following: (a) appropriate installations, trained staff and approved procedures must be disposed for sampling, inspection and testing materials, packaging materials and intermediate products, bulk and finished , and when appropriate to monitor environmental conditions for GMP purposes; (b) Samples of starting materials, packaging materials, intermediate products, bulk products and finished products should be collected by all and personnel approved by the CQ department; (c) qualification and validation; WHO TECHNICAL REPORT SERIES IN 986, 2014 (D) records must be made (manually and/or record instruments) demonstrating that all sampling, inspection and testing procedures were actually performed and what any deviations were fully registered and investigated; 130 (e) Finished products must contain ingredients in accordance with the qualitative and quantitative composition of the product described in the marketing authorization; The ingredients must be of necessary purity, in their proper container and properly labeled; (f) Records must be made from the results of the inspection and testing of materials and intermediate products, in bulk and finished in relation to specific specifications; The evaluation of the product must include a review and evaluation of the relevant production documentation and an evaluation of deviations from specified procedures; (g) sufficient samples of materials and starting products must be retained to allow future examination of the product if necessary; The retained product should be kept for the appropriate time in its final package, unless the is exceptionally large, in this case, that it is equivalent to theThe packaging system can be used Annex 17.4 Other responsibilities of CQ include: (a) establishment, validation and implementation of all CQ procedures; (b) evaluate, maintain and store refinement patterns for substances; (c) ensure the correct labeling of materials and products containers; (d) ensure that the stability of active ingredients and pharmacoms are monitored; (E) participate in the investigation of related complaints to the quality of the product; (F) participating in environmental monitoring; (g) Participation in QMM programs these activities must be performed in accordance with written procedures and, when necessary, registered 17.5 staff of CQ must have access to produce For sampling and investigation as appropriate control of departure materials and intermediate products, mass and finished 17.6 All tests must follow the instructions provided in the written test procedure relevant for each material or product, The result should be verified by the supervisor before the material or product is released or rejected, 17.7 samples must be representative of the material lots of which they are taken according to the written procedure approved 17.8 The sampling must be performed to avoid contamin £ o or other adverse effects on quality, the containers that have been sampled should be marked according to and carefully the sampling of 17.9 care that should be taken during sampling to protect C Ontra against contamination or mixture of, or by, the material bein g sampled in all sampling equipment that come into contact with the material should be clean, some particularly dangerous or powerful materials may require special precautions 17.10 equipment sampling should be cleaned and, if necessary, sterilized before and after each use and stored separately from other equipment 131 WHO Specifications for Forty and Eighth Eighth Pharmacon Preparations 17.11 Each sample container shall withstand a label indicating: (a) (b) (c) (d) (e) (f) the name of the sampled material; the number of the lot or lot; the number of the containment from which the sample was obtained; the number of the sample; the signature of the person who took the sample; The 17.12out-OF-Specification Results Sampling Date Obtained during the Materials or Product Test should be investigated according to approved procedures records, test test requirements and packaging materials 17.13 before release an initial material or Packaging for use, QC the manager must ensure that the materials have been tested as to the compliance with the identity, force, purity, and other quality parantees that the reporting reports are 986, 2014 17.14an Identity test should be performed in a sample of each starting material container (see also section 14.14) is allowed to prove only a proposal of the containment in which a procedure Validated has been established to ensure that no starting material containment has been labeled incorrectly that this validation must take into account at least the following aspects: 132 - "" "" ¢ â € Naturez a and the status of the manufacturer and supplier and its understanding of the GMP requirements; - The quality control system of the initial material manufacturer; - The factory conditions under which the initial material is produced and controlled; - The nature of the initial material and the medicines in which it will be used under such a system, it is possible that a procedure validated for the requirement for the identity test of each starting material container may be accepted by Next: - Initial materials from a manufacturer or fan of products; or annex - starting materials directly from a manufacturer or in the Sealed container where there is a history of reliability and regular audits of the manufacturer's quality control system conducted by the buyer (the drug manufacturer) or by an officially accredited rise, it is improvable that this procedure may be satisfactorily validated to: - Initial materials provided by intermediates, such as brokers, where the source of manufacture is unknown or not audited; or starting materials for use in parenteral products 17.15ech lot (lot) of printed packaging materials should be examined after receipt 17.16 instead of complete testing of the manufacturer, a certificate of dwarf may be accepted from the supplier, provided that the Manufacturer establishes the reliability of the supplier's dwarf through the appropriate perion validation of supplier test results (see sections 8.8 and 8.9) and through audits at the venue of the supplier resources (This is not affectionate 17.15.) Certificates must be original (no photocancies) or otherwise have their certificates guaranteed by authenticity must contain at least the following information (7): (a a) Identification (name and address) of the issuing supplier; (b) signature of the competent employee and declaration of their qualifications; (c) the name of the material tested; (d) the number of the lot of the material tested; (E) the specifications and mothers use; (f) the results of the test obtained; (g) The process of control test in process 17.17 The control records in process must be maintained and part of the records in lot (see 15.25) finished products 17.18 for each batch of medicines, there must be one appropriate laboratory determination of satisfaction compliance with its end specific specification before release 133 WHO Committee of specific specification for specification for Farmauctic Preparations Forty and eighth Report 17.19 Products Failure to attend At Other relevant quality critics must be rejected Batch Record Review 17.20 QC Records must be reviewed as part of the process of approval of the Lot Liberation before the transfers to the authorized person any difference or failure of a Lot to meet their specifications must be carefully investigated the investigation must, if necessary, extend to other lots of the same product and other products that may have been associated with the specific or discrepany failure A written record of the investigation must be made and should include the conclusion and follow -up of 17.21 retention samples of each batch of finished product must be kept for at least one year ap. Expiration date The finished products should be kept usually in their final packaging and stored under the recommended conditions if exceptionally large packages are produced, smaller samples can be stored in appropriate containers. Samples of active starting materials must be maintained for at least one year of the expiration date of the corresponding finished product. Other initial materials (except solvents, gases and water) should be kept by a two -year -old if their stability allows materials and products to be reheated samples should be enough to allow at least two reviews Complete Stability Studies WHO SÃ © Rie of Tantial Report in 986, 2014 17.22QC should evaluate the quality and stability of finished pharmacoms and, when necessary, of the initial materials and intermediate products 134 17.23 documented characteristics and evidence that these tests indicate stability; (c) provisional for the inclusion of a sufficient number of lots; (d) the test schedule for each medicine; (E) provisional for special storage conditions; Annex (f) provisional for the retention of adequate samples; (g) A summary of all data generated, including evaluation and study conclusions 17.25 Stability must be determined before marketing and significant changes, for example, in processes, equipment or packaging materials Referements to good manufacturing practices for pharmacomatic products Products in: Committee of specific specification of WHO for preparation pharmaceuticals trigionously reported geneva, organizations World of Saãºde, 2003 (SA RIE OF WHO TOURS, No. 908), VALIDATION OF ANALATHIC PROCEDURES USED IN THE EXAMINATION OF PHARMAC MATERIALS IN: WHO Specialists Committee on Specific Specialists Committee For pharmacomatic preparations thirty and according to Geneva, World Health Organization, 1992 (SA RIE OF WHO TOURS REPORTS, No. 823), Annex EURAX-DIRETRIES OF THE BODE MANUFACTURING PRORTS (GMP (GMP) (http: //ec.euro pa.eu. /Health/documents/eudralex/vol-4/index_en.htm) PHARMACTICAL INSPECTION, COOPERATI OF SCHOOL INSPECTION (PIC/S) For Medicinal Plants Geneva, PIC/S Secretariat, 2000 Quality Guarantee of PharmaceuticalS WHO Guidelines, Related Guidelines and Training Mother GXP Geneva, World Wide Organization, 2013 (CD-ROM) Fabrication tics for pharmacoms, departs one în: Committee of Specialties of WHO specifications for pharmacation preparations thirty and according to Geneva Reporting, the World of Saãºde, 1992 (SA RIE OF REPORT WHO, No. 823), Annex 1; is at: quality of pharmacoms of pharmacoms a composition of related guidelines and materials vol 2, 2nd updated edition good practices of manufacturing and E Geneva, World Wide Organization, 2007; and in: quality guarantee of pharmacoms of pharmacoms, guidelines, related guidelines and formation dates GXP Geneva, world organization of Saãºde, 2013 (CD-ROM) Certified dwarf model in: Committee Specialist From the WHO on specifics for preparation pharmacoms trigger Trigue Sixth Geneva Report, the World of Sao of the Sao, 2002 (WHO Technical Report Series, 902), Annex 10 135 ... Pharmaceutical Prostics , Part one in: WHO Specialist Committee on Specifications for Pharmacies Thirty Pharmacies According to Geneva Report, World Cup Organization, 19 92, Annex (Who Technical - Xem Thãmm - Xemmm - Xem Thãm - Xemm - Xemm THERM - XEM THERM ... TEST REQUIREMENTS MANAGEMENT OF LOT RECORDS STABILITY STUDIES REFERENCES 115 116 125 126 127 128 129 131 1 32 134 135 Annex Introduction The first text of WHO ... Text. ..

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